

***Detailed Action***

Applicant's amendment filed on 03-15-2010 has been entered. Claims 1, 2, 5, 7, 9, 11, 13, 17, 18, 21, 23 and 25 are pending and not claims 1, 2, 4, 5, 7, 9, 11, 13, 17, 18, 21, 23 and 25 as Applicants contend at page 5, first line, of the remarks filed on 03-15-2010. Claims 22, 24 and 26 have been cancelled and claims 1, 9 and 13 have been amended by Applicants' amendment filed on 03-15-2010.

The Examiner contacted Applicant's representative on June 18, 2010 to discuss the merits of Applicants' amended claims filed on 03-15-2010. The Examiner proposed an amendment to the pending claims to set them forth in condition for allowance.

Authorization for the Examiner's amendment was given in a telephone interview with Peter Bernstein, on July 02, 2010. With respect to the proposed claims, an Examiner's amendment to the records appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the issue fee.

With respect to the proposed claims, an examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the issue fee.

***In the claims,***

Correct claim 1 as follows:

Page 1, line 2 of claim 1, the phrase "throughout life" is deleted.

Add claim 27 as follows:

Claim 27. The method of claim 13, wherein said second probiotic organism is a *Lactobacillus* selected from the group consisting of *L. rhamnosus*, *L. acidophilus*, *L. fermentum*, *L. casei*, *L. reuteri*, *L. crispatus*, *L. plantarum*, *L. paracasei*, *L. jensenii*, *L. gasseri*, *L. cellobiosus*, *L. brevis*, *L. delbrueckii*, *L. helveticus*, *L. salivarius*, *L. collinoides*, *L. buchneri*, *L. rogosae*, or *L. bifidum*.

### ***Reasons for allowance***

The following is an examiner's statement of reasons for allowance: The prior art of record does not teach or suggest of

A method for establishing a healthy bacterial flora in females, comprising administering a therapeutically effective amount of a first probiotic *Lactobacillus iners* and a pharmaceutically acceptable carrier, wherein said *Lactobacillus iners* is administered orally or vaginally, and administering a therapeutically effective amount of a second probiotic organism, the second probiotic organism being different than the first one.

### ***Rejections/Objections withdrawn in response to Applicant arguments or amendments:***

#### ***Claim Rejections - 35 USC § 103***

In view of Applicants' amendment of claims 1, 9 and 13, the previous rejection of claims 1, 2, 5, 7, 9, 11, 13, 17, 18, 21, 23 and 25 under 35 U.S.C. 103(a) as being unpatentable over Chrisope et al., (US Patent 6,468,526, Date of filing Dec 21, 2001), as evidenced by Macfarlane et al (1999, BMJ pp. 999-1003), in view of Hans et al., (US Patent 7,220,418; Date of PCT Publication Jan. 11, 2001) and further in view of Falsen et al., (1999, Journal of Systematic Bacteriology, pp. 217-221) has been withdrawn.

The combined disclosure of Chrisope et al., Macfarlane et al., Hans et al., and Falsen does not teach or suggest use *Lactobacillus iners* as a probiotic and a pharmaceutically acceptable carrier in a method for improving bacterial vaginal microbiota of women.

Of note, PCR-denaturing gradient gel electrophoresis (DGGE) and sequencing for bacterial identification of the invention achieved detection of *Lactobacillus iners* Y16329 as the most commonly recovered species of *Lactobacillus* in vaginal samples before and after probiotic installation. Thus *Lactobacillus iners* Y16329 appears to be the predominant species colonizing the vagina. Also note that Falsen et al., discloses the isolation of *Lactobacillus iners* Y16329 vaginal discharge, however, discharged vaginal fluid may contain beneficial or detrimental *Lactobacillus*. Falsen does not provides a rational about why *Lactobacillus iners* is important in a healthy vaginal flora.

#### ***Claim Rejections - 35 USC § 112-Deposit Requirement***

In view of Applicants' cancellation of claims 22, 24 and 26 and further in view that species *Lactobacillus iners*, Genbank-Y16329 nucleotide sequence was known in the art and available to the public at the time the invention was made (see search result 1 and Genebank sequence search for Y16329 ), rejection of claims 21-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn.

#### ***Conclusion***

Claims 1, 2, 5, 7, 9, 11, 13, 17, 18, 21, 23 and 25 are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maria Leavitt/

Maria Leavitt  
Primary Examiner, Art Unit 1633